

REMARKS

I. Status of the Claims

Claims 39 and 41-55 are pending in the application. No claims have been amended in this response.

II. The Finality of the Office Action is Premature

The Office Action mailed on October 4, 2004 was made final, but no reasons supporting the propriety of making the Office Action final were provided.

In the final Office Action, three new citations that were not previously of record were cited. None of these three new citations were submitted in an information disclosure statement filed by Applicant after submission of the previous response. Also, Applicant's amendment of the claims did not necessitate any new grounds of rejection based on these citations.

Because no reasoning or support was provided indicating why the Office Action was made final, and because multiple new grounds of rejection (based on newly identified citations) were issued, the finality of the Office Action is premature. Applicant respectfully requests withdrawal of the premature finality of the Office Action.

III. Status of Petitions for Correction of Inventorship

As stated in the previous response, Applicant has filed two petitions under 37 C.F.R. for correction of inventorship. The first petition was filed to add Dale Whipple as an inventor. The second petition was filed to remove Dale Whipple as an inventor, as Dale Whipple is not an inventor of the subject matter that was elected in response to the restriction requirement. No decision on either petition has been received, and no comments or remarks were provided by the Examiner regarding the status of these petitions in the final Office Action.

Applicant respectfully requests the status of these petitions.

IV. An Audiovisual Representation Will Be Forwarded in a Supplemental Response

To facilitate the Examiner's understanding of the numerous differences between the subject matter of the present claims and the citations relied on by the Examiner, an audiovisual representation will be forwarded to the Examiner in a supplemental response.

V. Each of Claims 41, 47, 48 and 54 Meets the Written Description Requirement of 35 U.S.C. § 112 First Paragraph

Claims 41, 47, 48 and 54 are each rejected under § 112, first paragraph as failing to comply with the written description requirement. Applicant traverses the rejection.

It is well established that the subject matter of a claim need not be described literally in order for the disclosure to satisfy the written description requirement. Instead, the test is does the disclosure of the application relied upon "reasonably convey to the artisan that the inventor had possession at that time of the later claimed subject matter." *Ralston Purina Co. v. Far-Mar-Co., Inc.*, 772 F.2d 1570, 1575, 227 USPQ 177, 179 (Fed. Cir. 1985) (quoting *In re Kaslow*, 707 F.2d 1366, 1375, 217 USPQ 1089, 1096 (Fed. Cir. 1983)). The claims may be supported by words, structures, figures, diagrams, and formulas that fully set forth the claimed invention. *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997).

When this test is properly applied to claims 41, 47, 48 and 54, each of claims 41, 47, 48 and 54 is fully supported by the specification, figures, abstract and claims as originally filed (hereafter collectively referred to as "the disclosure"). Support for claim 41 may be found, for example, at page 26, line 16 to page 27, lines 8-9, page 27, lines 8-9 (stating "a surgical incision is not created to expose the anchoring tissues"), page 27, line 23, FIGS. 12-14 and throughout the disclosure. Support for claim 47 may be found, for example, at page 27, lines 16-23, page 39, lines 16-23, at original claim 33 and throughout the disclosure. Support for claim 48 may be found, for example, page 39, lines 4-5, page 39, line 22 and throughout the disclosure. Support for claim 54 may be found, for example, at FIGS. 12-14, 23 and at page 11, lines 16-19, page 27, lines 8-9 and throughout the disclosure.

With particular reference to claim 54, claim 54 has been rejected under 35 U.S.C. § 112, first paragraph, but no objective evidence that challenges the validity of claim 54 has been provided. The Examiner bears the initial burden of presenting by a preponderance of evidence why a person skilled in the art would not recognize in Applicant's disclosure a description of the

invention defined by the claims. See *In re Wertheim*, 541 F.2d 257, 263, 191 USPQ 90, 97 (CCPA 1976). No such evidence has been provided regarding claim 54, and, therefore, claim 54 meets the requirements of 35 U.S.C. § 112, first paragraph.

In view of the above, each of claims 41, 47, 48 and 54 meets the written description requirement of 35 U.S.C. § 112, first paragraph. Applicant respectfully requests withdrawal of the rejection.

V. Claims 39, 41, 46-49 and 52-55 are Patentable over Kovac

Claims 39, 41, 46-49 and 52-55 are rejected under § 102(e), or in the alternative under § 103(a), over Kovac (US 6,039,686). Applicant traverses the rejection.

Each of claims 39, 41, 46-49 and 52-55 is patentable over Kovac. Kovac is representative of existing, conventional surgical techniques used to treat stress incontinence, many of which are discussed in the “Background” section of the specification. See pages 3-4 of the specification. Kovac’s methods are designed to suspend the urethra. In contrast, the instant claims are methods of paravaginal repair or vaginal repair.

Kovac uses a prosthetic device, i.e., a sling, to support the urethra. See Abstract; Col. 3, lines 53-56; Col. 5, lines 52-56 of Kovac. The sling is anchored to the pubic bones (See Col. 3, lines 11-13; claim 1) using anchor screws (Col. 6, lines 42-55). Kovac’s use of a prosthetic device anchored to bone to support the urethra is insufficient to render any of claims 39, 41, 46-49 and 52-55 unpatentable.

Kovac also expressly teaches away from the subject matter of claims 39, 41, 46-49 and 52-55. Kovac states at Col. 8, lines 2-10 that

It is generally believed (as indicated above) that urethral hypermobility is caused by deficiencies in the arcus tendineus fascia pelvis and the pubourethral ligaments. In addition, the pubourethral ligaments are subject to stretching or elongation. *None of these damaged, or elongated, or deficient muscular and fascial paraurethral tissues* is used to supply the support and stabilization provided by the system of the present invention. [emphasis added]

In contrast to the prosthetic device used in Kovac, the subject matter of each of claims 39, 41, 46-49 and 52-55 uses existing anatomical structures to accomplish the vaginal or paravaginal repair. In claim 39, at least one of a superior lateral sulci or inferior lateral sulci is

approximated to the lateral pelvic sidewall without exposing the lateral pelvic sidewall through a surgical incision in a vaginal wall. Claim 53 depends directly from claim 39 and incorporates the language of claim 39 through dependency. In claim 41, a vaginal epithelium is approximated to at least one of a lateral pelvic sidewall and a sacrospinous ligament without exposing at least one of the lateral pelvic sidewall and the sacrospinous ligament through a surgical incision in the vaginal epithelium. Each of claims 46-49 and 54 depends directly or indirectly from claim 41 and incorporates the language of claim 41 through dependency. In claim 52, a first soft tissue is affixed to a second soft tissue without exposing one of the first tissue and the second tissue through a surgical incision in the other tissue. Claim 55 depends directly from claim 52 and incorporates the language of claim 52 through dependency. Thus, the methods defined by claims 39, 41, 46-49 and 52-55, which, in part, approximate a first anatomical structure to a second anatomical structure, differ from the bone anchored prosthetic device used in the support method of Kovac. Accordingly, Kovac's teaching of a sling anchored to the pubic bones is insufficient to anticipate, or render obvious, any of claims 39, 41, 46-49 and 52-55.

With particular reference to claim 39, Kovac fails to disclose, teach or suggest a method of surgical paravaginal repair comprising, in part, approximating at least one of the superior lateral sulci and inferior lateral sulci to the lateral pelvic sidewall without exposing the lateral pelvic sidewall through a surgical incision. The particular anatomical structures recited in claim 39 may not be ignored but must be given due weight and consideration in interpreting the subject matter of claim 39.

In contrast to claim 39, Kovac makes a pair of divergent incisions beginning at the posterior urethral fold and separates the anterior vaginal wall between the incisions to form a triangular vaginal wall flap (See Col. 3, lines 32-40; Col. 6, lines 9-18; FIGS. 5 and 6) to provide access to the urethra and pubic bone. Such a teaching is opposite to the subject matter defined by claim 39. That is, Kovac is opposite to a method of surgical paravaginal repair comprising placing a soft tissue fixation device vaginally through an insertion device adapted for inserting the soft tissue fixation device, and approximating at least one of the superior lateral sulci and inferior lateral sulci to the lateral pelvic sidewall without exposing the lateral pelvic sidewall through a surgical incision in a vaginal wall. Therefore, Kovac does not anticipate claim 39 or render claim 39 obvious.

With particular reference to claim 41, Kovac does not disclose, teach or suggest a method of surgical repair using a soft tissue fixation device and an insertion device, wherein the surgical repair is one of a paravaginal repair and a vaginal repair, the method comprising placing the soft tissue fixation device vaginally through the insertion device, and approximating a vaginal epithelium to at least one of a lateral pelvic sidewall and a sacrospinous ligament without exposing at least one of the lateral pelvic sidewall and the sacrospinous ligament through a surgical incision in the vaginal epithelium. Therefore, Kovac does not anticipate claim 41 or render claim 41 obvious.

The Examiner asserts in numbered paragraph 6 on page 4 of the Office Action, that “an insertion device [in Kovac] is obvious if not inherent.” To establish inherency, the Examiner bears the burden of demonstrating that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. *Continental Can Co. USA v. Monsanto Co.*, 948 F.2d 1264, 1268, 20 USPQ2d 1746, 1749 (Fed. Cir. 1991). This burden is not satisfied merely by asserting inherency. No proper objective evidence has been presented demonstrating that Kovac necessarily discloses an insertion device, as that term is used in the present claims.

In view of the above, each of claims 39, 41, 46-49 and 52-55 is patentable over Kovac. Applicant respectfully requests withdrawal of the rejection.

VI. Claims 39, 41, 46-49 and 52-55 are Patentable over Benderev

Claims 39, 41, 46-49 and 52-55 are rejected under § 102(e), or in the alternative under § 103(a), over Benderev (U.S. 6,500,194). Applicant traverses the rejection.

First, there is no disclosure, teaching or suggestion in Benderev of vaginal repair or paravaginal repair that comprises, at least in part, approximating the particular anatomical structures recited in claims 39, 41, 46-49 and 52-55. The specific anatomical structures recited in the claims must be provided proper and due consideration in interpreting the claims. When the particular anatomical structures recited in claim 39 are given proper consideration, Benderev fails to anticipate or render claim 39 obvious. In particular, Benderev fails to disclose, teach or suggest a method of surgical paravaginal repair comprising, in part, approximating at least one of the superior lateral sulci and inferior lateral sulci to the lateral pelvic sidewall without exposing

the lateral pelvic sidewall through a surgical incision. Instead, Benderev suspends the neck of the bladder using a staple or sutures attached to a suture support. A bone anchor is used to fix the suture to bone. See Example III in Col. 38 and 39. Thus, claim 39 is patentable over Benderev. Claim 53 depends directly from claim 39 and is patentable over Benderev for at least the same reasons.

Likewise, when the anatomical structures of claim 41 are properly considered, Benderev fails to anticipate or render claim 41 obvious. In particular, Benderev fails to disclose, teach or suggest a method of vaginal repair or paravaginal repair comprising, in part, approximating a vaginal epithelium to at least one of a lateral pelvic sidewall and a sacrospinous ligament without exposing at least one of the lateral pelvic sidewall and the sacrospinous ligament through a surgical incision in the vaginal epithelium. Instead, Benderev suspends the neck of the bladder using a staple or sutures attached to a suture support. A bone anchor is used to fix the suture to bone. See Example III in Col. 38 and 39. Thus, claim 41 is patentable over Benderev. Each of claims 46-49 and 54 depends directly or indirectly from claim 41 and is patentable over Benderev for at least the same reasons.

Second, Benderev is similar to Kovac in that Benderev is representative of existing, conventional surgical techniques used to treat stress incontinence. Benderev's methods are designed to suspend the bladder neck and are not directed to vaginal repair or paravaginal repair, as recited in claims 39, 41, 46-49 and 52-55. Thus, the present claims and Benderev are directed to entirely different methods.

Benderev is generally directed to drill guides and bone anchor installation. See Summary. Benderev anchors a sling formed from sutures to the pubic bones. Even though Benderev describes the use of a staple applier for suspending tissues (Col. 4, lines 27-31 and Col. 38), this usage of the staples is still described as being used "in conjunction with the bladder neck suspension procedure" described in Benderev. See Col. 38, lines 33-34. In numerous instances Benderev discusses placement of a sling for a bladder suspension procedure. Benderev states at column 19, lines 8-10, "there is provided a suture passer adapted for grasping and passing internal sutures, such as to construct *the sling disclosed herein*" [emphasis added]. At Col. 23, lines 11-12, Benderev discusses a suture tensioner for providing repeatable amounts of slack in the suture sling. Benderev also emphasizes the importance of bone anchoring. For

example, Benderev emphasizes the importance of placing a bone anchor into the pubic bone for the bladder neck suspension, stating at Col. 10, lines 5-7 that “care must be taken to assure that the hole has been drilled into the pubic bone.” In view of the above, Benderev is directed to placement of a sling, which is anchored to the bone, to suspend the bladder. Benderev’s method is designed to suspend the bladder to treat stress incontinence, and is not directed to vaginal repair or paravaginal repair.

In contrast to the sling used in Benderev, the subject matter of claims 39, 41, 46-49 and 52-55 uses existing anatomical structures for vaginal repair or paravaginal repair. In claim 39, at least one of a superior lateral sulci or inferior lateral sulci is approximated to the lateral pelvic sidewall without exposing the lateral pelvic sidewall through a surgical incision in a vaginal wall. Claim 53 depends directly from claim 39 and incorporates the language of claim 39 through dependency. In claim 41, a vaginal epithelium is approximated to at least one of a lateral pelvic sidewall and a sacrospinous ligament without exposing at least one of the lateral pelvic sidewall and the sacrospinous ligament through a surgical incision in the vaginal epithelium. Each of claims 46-49 and 54 depends directly or indirectly from claim 41 and incorporates the language of claim 41 through dependency. In claim 52, a first soft tissue is affixed to a second soft tissue without exposing one of the first tissue and the second tissue through a surgical incision in the other tissue. Claim 55 depends directly from claim 52 and incorporates the language of claim 52 through dependency. Thus, the methods defined by claims 39, 41, 46-49 and 52-55, which approximate a first anatomical structure to a second anatomical structure, differ from the bone anchored sling used in the bladder suspension method of Benderev. Accordingly, Benderev’s teaching of a sling is insufficient to anticipate, or render obvious, any of claims 39, 41, 46-49 and 52-55.

Also, Benderev expressly leads away from affixing a first tissue to a second tissue as recited in claim 52. At Col. 29, line 63 to Col. 30, line 3, Benderev states

there is provided a suture support which is used to anchor sutures with respect to soft tissue inside the body. The suture support reduces the trauma to internal body tissue which can occur when a suture is tied off solely in tissue, by increasing the tissue area which supports the forces exerted by the suture. In the context of a bladder neck suspension procedure, the suture support is intended to keep a suture from pulling through the vaginal wall tissue.

Thus, Benderev teaches away from affixing a first tissue to a second tissue, because Benderev teaches that trauma will result from increased forces from the sutures used in Benderev. Instead, Benderev teaches the use of a suture support. In contrast, claim 52 recites affixing the first tissue to a second tissue without exposing one of the first tissue and the second tissue through a surgical incision in the other tissue. Accordingly, Benderev does not anticipate claim 52 of render claim 52 obvious. Claim 55 depends directly from claim 52 and is patentable over Benderev for at least the same reasons.

In view of the above, each of claims 39, 41, 46-49 and 52-55 is patentable over Benderev. Applicant respectfully requests withdrawal of the rejection.

VII. Claims 42 and 43 are Patentable over Kovac or Benderev in view of Thompson

Claims 42 and 43 are rejected under § 103(a) over Kovac or Benderev in view of Thompson (U.S. 5,591,163). Applicant traverses the rejection.

Each of claims 42 and 43 depends directly from claim 41. As discussed above in Sections V. and VI., neither Kovac nor Benderev can be properly applied to claim 41 because they fail to disclose, teach or suggest each and every element of claim 41. In particular, the anatomical structures recited in claim 41 are not disclosed as being used by the methods in Kovac and Benderev, and the stress incontinence treatment methods of Kovac and Benderev are vastly different from the vaginal repair or paravaginal repair method defined by claim 41. For similar reasons, the combination of Kovac with Thompson or Benderev with Thompson cannot be properly applied to claim 41 or any claim that depends from claim 41.

Notwithstanding that it is improper to apply either Kovac or Benderev to claim 41 or any claim that depends from claim 41 (e.g., claims 42 and 43), Thompson still fails to cure the deficiencies of either Kovac or Benderev. In particular, Thompson's method is designed to treat stress incontinence by suspending the urethra from an anchor attached above the urethra. See Abstract; Col. 3, lines 62-64; Col. 4, lines 48-49. Thompson uses an anchor secured in the pubic bone to suspend the urethra. See Col. 6, lines 1-8. The tails of sutures are tied together to form a sling to suspend the urethra. See Col. 6, lines 8-19. Accordingly, the methods of Thompson, which use a bone anchored sling, are similar to the methods of Kovac and Benderev, and Thompson cannot be applied to the present claims.

In view of the above, claims 42 and 43 are not anticipated by Kovac in combination with Thompson or by Benderev in combination with Thompson. Applicant respectfully requests withdrawal of the rejection.

VIII. Claims 44, 45, 50 and 51 are Patentable over Kovac or Benderev

Claims 44, 45, 50 and 51 are rejected under § 103(a) over Kovac or over Benderev. Applicant traverses the rejection.

Each of claims 44, 45, 50 and 51 depends directly or indirectly from claim 41. As discussed above in Sections V. and VI., neither Kovac nor Benderev can be properly applied to claim 41 because they fail to disclose, teach or suggest each and every element of claim 41. In particular, the anatomical structures recited in claim 41 are not disclosed as being used by the methods in Kovac and Benderev, and the methods of Kovac and Benderev are vastly different from the method defined by claim 41. Thus, neither Kovac nor Benderev render any of claims 44, 45, 50 and 51 obvious.

Applicant respectfully requests clarification of the remarks in numbered paragraph 11 on pages 7-8 of the Office Action. In particular, the Examiner has asserted that claims 44 and 45 are directed to a particular species. Claim 44, however recites the additional step of “providing a remover,” and claim 45 recites the additional step of “removing the soft tissue fixation device that is malpositioned by traction.” Such additional steps should be properly considered in interpreting the subject matter of claims 44 and 45. Applicant does not understand how such additional steps can be interpreted as a species that “can be considered equivalents.” Applicant respectfully requests clarification of these remarks.

With reference to claims 50 and 51, the Examiner has made the unsupported assertion that because MRI, CT scans, etc. are well known, the subject matter of each of claims 50 and 51 is somehow obvious. Such an unsupported assertion does not establish obviousness.

Instead, it is well established that the test for obviousness includes three parts. First, the citation(s) must teach or suggest all of the claimed features. Second, there must be some specific suggestion or motivation, either in the cited citation(s) or in the knowledge generally available to one of ordinary skill in the art, to modify the citation(s). Third, there must be a reasonable expectation of success. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).


Applying the obviousness test to claims 50 and 51, first and as discussed above, neither Kovac nor Benderev teach or suggest all the features of claim 41. Because each of claims 50 and 51 depends directly from claim 41, Kovac and Benderev necessarily cannot teach or suggest all the features of claim 50 or claim 51. Second, no objective evidence has been identified that Kovac or Benderev teaches or suggests use of the modalities listed in each of claims 50 and 51. When no such teaching or suggestion exists, obviousness is not established. Third, no reasonable expectation of success has been identified. Accordingly, none of the three criteria for establishing obviousness has been met in the present case.

In view of the above, Applicant requests withdrawal of the rejection.

IX. Conclusion

In view of the above remarks, all claims pending in the application are in condition for allowance. Applicant respectfully requests withdrawal of all rejections and issuance of a Notice of Allowance.

Respectfully submitted,
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